

## 5. Exposure and Risk Assessment

*Risk Quotients (RQs) and the Levels of Concern (LOCs).* In order to integrate exposure information with toxicity information, a risk quotient (RQ) is calculated by dividing exposure

$$\text{Risk Quotient} = \frac{\text{Exposure}}{\text{Toxicity}}$$

Examples of toxicity measurements used in the calculation of RQs are:

- LC<sub>50</sub> (fish and amphibians; birds)
- LD<sub>50</sub> (birds and mammals)
- EC<sub>50</sub> (aquatic plants and invertebrates)
- EC<sub>25</sub> (terrestrial plants)
- EC<sub>05</sub> or NOAEC (endangered plants)

To assess whether there is an ecological concern, RQ values are compared to Levels of Concern (LOCs). The LOCs depend on whether the Toxicity measurement represents acute or chronic toxicity, and there are different LOCs for the acute RQs (see table below). The Agency interprets exceedances of LOCs as follows:

- *acute high risk* - potential for acute risk is high; regulatory action may be warranted in addition to restricted use classification;
- *acute restricted use* - the potential for acute risk is high, but this may be mitigated through restricted use classification;
- *acute endangered species* - the potential for acute risk to endangered species is high; regulatory action may be warranted;
- *chronic risk* - the potential for chronic risk is high; regulatory action may be warranted.

Risk presumptions, along with the corresponding RQs and LOCs are tabulated below.

### Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ formula <sup>[1]</sup>	LOC
<b>Birds</b>		
Acute High Risk	EEC / LC50 or EEC / LD50/ft <sup>2</sup> or EEC / ( LD50/day <sup>[3]</sup> )	0.5
Acute Restricted Use	EEC / LC50 or EEC / LD50/ft <sup>2</sup> or EEC / ( LD50/day ) (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC / LC50 or EEC / LD50/ft <sup>2</sup> or EEC / LD50/day	0.1
Chronic Risk	EEC / NOAEC	1
<b>Wild Mammals</b>		
Acute High Risk	EEC / LC50 or EEC / LD50/ft <sup>2</sup> or LD50/day	0.5
Acute Restricted Use	EEC/LC50 or LD50/ft <sup>2</sup> or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/ft <sup>2</sup> or LD50/day	0.1
Chronic Risk	EEC/NOAEC	1

<sup>[1]</sup> abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

<sup>[2]</sup>  $\frac{\text{mg/ft}^2}{\text{LD50} * \text{wt. of bird}}$  <sup>[3]</sup>  $\frac{\text{mg of toxicant consumed/day}}{\text{LD50} * \text{wt. of bird}}$

### Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC / LC50 or EEC / EC50 <sup>[1]</sup>	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/NOAEC	1

<sup>[1]</sup> EEC = (ppm or ppb) in water

### Risk Presumptions for Plants

Risk Presumption	RQ	LOC
<b>Terrestrial and Semi-Aquatic Plants</b>		
Acute High Risk	EEC / EC25 <sup>[1]</sup>	1
Acute Endangered Species	EEC/EC05 or EEC / NOAEC	1
<b>Aquatic Plants</b>		
Acute High Risk	EEC / EC50 <sup>[2]</sup>	1
Acute Endangered Species	EEC/EC05 or EEC / NOAEC	1

<sup>[1]</sup> EEC = lbs ai/A

<sup>[2]</sup> EEC = (ppb/ppm) in water

### **a. Exposure and Risk to Nontarget Terrestrial Animals**

For pesticides applied as a nongranular product (e.g., liquid, dust), the estimated environmental concentrations (EECs) on food items following product application are compared to LC50 values to assess risk. The predicted 0-day maximum and mean residues of a pesticide that may be expected to occur on selected avian or mammalian food items immediately following a direct single application at 1 lb ai/A are tabulated below.

Estimated Environmental Concentrations on Avian and Mammalian Food Items (ppm) Following a Single Application at 1 lb ai/A)

Food Items	EEC (ppm)	EEC (ppm)
	Predicted Maximum Residue <sup>1</sup>	Predicted Mean Residue <sup>1</sup>
Short grass	240	85
Tall grass	110	36
Broadleaf/forage plants, and small insects	135	45
Fruits, pods, seeds, and large insects	15	7

<sup>1</sup> Predicted maximum and mean residues are for a 1 lb ai/a application rate and are based on Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994).

Predicted residues (EECs) resulting from multiple applications are calculated in various ways. For this assessment, maximum ODM EECs were calculated using Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). These EECs served as inputs into the FATE program. The FATE program is a first order dissipation model, i.e., the pesticide is applied repeatedly, but degrades over time from the first application to the last application. The half-life used in the model was 3.2 days, the aerobic soil half-life (MRID 42830501).

### **i. Birds**

The acute risk quotients for broadcast applications of nongranular products of ODM are tabulated below. Maximum EECs result from the pesticide being applied repeatedly, but degrading over the course of time from the first application to the last application based on an assumption of first-order degradation kinetics. The LC50 for ODM active ingredient was estimated from an LC50 based on testing of formulated product with 50% active ingredient. An extrapolated LC<sub>50</sub> for the bobwhite quail was used to determine risk.

# Avian Acute Risk Quotients for Aerial Applications of ODM

Site/App. Method	App. Rate lbs ai/A (No. of Apps.)/Appl interval	Food Items	Maximum EEC <sup>1</sup> (ppm)	Acute RQ (EEC/ LC50) <sup>2</sup>
Cabbage and cotton/aerial	0.75 (3)/7 days	Short grass	228	1.05
		Tall grass	105	0.48
		Broadleaf plants/Insects	128	0.59
		Seeds	14	0.06
Corn and sorghum/aerial	0.5 (3)/7 days	Short grass	152	0.70
		Tall grass	70	0.32
		Broadleaf plants/Insects	86	0.40
		Seeds	10	0.05
Alfalfa/aerial	0.5 (2)/14 days	Short grass	126	0.58
		Tall grass	58	0.27
		Broadleaf plants/Insects	71	0.33
		Seeds	8	0.04
Citrus/air blast	0.375 (2)/14 days	Short grass	95	0.44
		Tall grass	43	0.20
		Broadleaf plants/Insects	53	0.24
		Seeds	5.8	0.03

<sup>1</sup> Assumes degradation using FATE program.

<sup>2</sup> Shading indicates an LOC has been exceeded.

The LC50 is 217 ppm active ingredient based on testing of formulated product with bobwhite quail.

The chronic risk quotients for broadcast applications of nongranular products of ODM are tabulated below. Maximum EECs result from the pesticide being applied repeatedly, but degrading over the course of time from the first application to the last application (FATE program). Average EECs, the average of the estimated daily concentrations over a period of time, were also derived from the FATE program.

Avian Acute and Chronic Risk Quotients for Multiple Aerial Applications of ODM Products Based on a Northern bobwhite quail NOAEC of 1.8 ppm.

Site/App. Method	App. Rate lbs ai/A (No. of Apps.)/Appl interval	Food Items	Maximum EEC <sup>1</sup> (ppm)	Average EEC <sup>1</sup> (ppm)	Average Chronic RQ (Ave. EEC/ NOAEC) <sup>2</sup>	Maximum Chronic RQ (Max. EEC/ NOAEC) <sup>2</sup>
Cabbage and cotton/aerial	0.75 (3)/7 days	Short grass	228	45	25.	127.
		Tall grass	105	21	12	58.
		Broadleaf plants/Insects	128	26	14.	71.
		Seeds	14	3	1.7	7.8
Corn and sorghum/aerial	0.5 (3)/7 days	Short grass	152	30	17.	84.
		Tall grass	70	14	7.8	39.
		Broadleaf plants/Insects	86	17	9.4	48.
		Seeds	10	2	1.1	6.7
Alfalfa/aerial	0.5 (2)/14 days	Short grass	126	20	11.	70.
		Tall grass	58	9	5.	32.
		Broadleaf plants/Insects	71	11	6.	39.
		Seeds	8	1	0.1	4.4
Citrus/air blast	0.375 (2)/14 days	Short grass	95	15	8.4	53.
		Tall grass	43	7	3.8	24.
		Broadleaf plants/Insects	53	8	4.7	29.
		Seeds	5.8	1	0.5	3.

<sup>1</sup> Assumes degradation using FATE program. <sup>2</sup>Shading indicates an LOC has been exceeded.

Based on both the maximum and average EECs, which assumed degradation using the FATE program, the avian chronic level of concern is exceeded for all modeled uses with the exception of seeds from the alfalfa use.

## ii. Mammals

**Acute risk.** Acute hazard to small mammals was addressed using the acute oral LD<sub>50</sub> value for the rat converted to an estimated LC<sub>50</sub> value for dietary exposure. The estimated LC<sub>50</sub> was derived using the following formula:

$$LC_{50} = LD_{50} * \text{body weight} / \text{weight food consumed per day}$$

with mass variables in the same units. Acute risk to mammals was assessed by calculating RQs for three representative species: the meadow vole, the field mouse, and the least shrew. Estimated mammalian LC<sub>50</sub> values for these three species of small mammals are presented below:

**Table F: Estimated Small Mammal Dietary Exposure (Based on an LD<sub>50</sub> = 48 mg/kg)**

Small Mammal	Body Weight (g)	Percent of Weight Eaten Per Day	Food Consumed Per Day (g)	Estimated LC <sub>50</sub> (ppm)
Meadow vole	46	61 %	28.1	79
Adult field mouse	13	16 %	2.1	297
Least shrew	5	110 %	5.5	44

The above table is based on information contained in Principles of Mammalogy by D. E. Davis and F. Golley, published by Reinhold Corporation, 1963.

The acute risk quotients are calculated by dividing the EECs (i.e. residues) by the estimated LC<sub>50</sub>'s. The table below shows the risk quotients for peak exposures of ODM.

**Table G: Mammalian Acute Risk Quotients**

Species and Diet	Use Site	Application Rate (lb ai/A)	Maximum EEC <sup>1</sup> in Food Item (ppm)	Risk Quotient <sup>2</sup>
Meadow vole consuming short grasses	Cabbage and cotton	0.75	228	2.9
	Corn and sorghum	0.5	152	2.0
	Alfalfa	0.5	126	1.6
	Citrus	0.375	95	1.2
Adult field mouse consuming seeds	Cabbage and cotton	0.75	14	0.05
	Corn and sorghum	0.5	10	0.03
	Alfalfa	0.5	8	0.03
	Citrus	0.375	5.8	0.02
Least shrew consuming insects	Cabbage and cotton	0.75	128	3
	Corn and sorghum	0.5	86	2.0
	Alfalfa	0.5	71	1.6
	Citrus	0.375	53	1

<sup>1</sup>Based on Hoeger and Kenaga (1972) with modifications by Fletcher et al. (1994) and assumes degradation using FATE program. <sup>2</sup>Shading indicates an LOC has been exceeded.

For all use sites, RQs for the meadow vole and the least shrew are greater than 0.5, the LOC for presumption of risk, 0.2, the LOC for restricted use, and 0.1, the LOC for presumption of risk to endangered species. This indicates that use of ODM on cabbage (representative of cole crops) and cotton, corn and sorghum, alfalfa, and citrus poses an acute risk to mammals, both endangered and non-endangered.

**Chronic Risk.** RQs were calculated for chronic effects of ODM to mammals.

Table H: Mammalian Chronic Risk Quotients (RQs) for ODM Applications Based on a Rat NOAEC of 9 ppm and Maximum EECs

Crop	Maximum Application Rate (lbs a.i./A)	Food Items	Average EEC (ppm) <sup>1</sup>	Chronic RQ (EEC/NOAEC) <sup>2</sup>
Cabbage and cotton	0.75	Short grass	45	5.0
		Long grass	21	2.3
		Broadleaf plants and insects	26	2.9
		Fruit	3	0.3
Corn and sorghum	0.5	Short grass	30	3.3
		Long grass	14	1.6
		Broadleaf plants and insects	17	1.9
		Fruit	2	1.3
Alfalfa	0.5	Short grass	20	2.2
		Long grass	9	1.0
		Broadleaf plants and insects	11	1.2
		Fruit	1	0.1
Citrus	0.375	Short grass	15	1.7
		Long grass	70	0.8
		Broadleaf plants and insects	8	0.95
		Fruit	1	0.1

<sup>1</sup>Based on Hoerger and Kenaga (1972) with modifications by Fletcher et al. (1994) and assumes degradation using FATE program. <sup>2</sup>Shading indicates an LOC has been exceeded.

All of the chronic RQs for mammals (for all the food items considered) exceed the LOC of 1 for use on cabbage and cotton, corn and sorghum, alfalfa, and citrus, with the exception of exposure on fruit from the alfalfa, cabbage and cotton, and citrus use. These results indicate that all uses of ODM pose a risk of causing chronic effects to mammals and may cause chronic adverse effects to threatened and endangered species of mammals.

The specific responses of the tested organisms in the study yielding the 9 ppm NOEL were decreases in male fertility and female fertility of unknown origin in the P and F<sub>1</sub> generations. Adult brain cholinesterase inhibition was noted at levels as low as 1 ppm. The data suggests a high risk of reproductive impairment and brain cholinesterase inhibition to mammals at any application level.



### **iii. Insects**

Currently, the Agency does not have formal Levels of Concern for assessing concerns for nontarget insects. Results of acceptable toxicity studies with the honey bee are used for recommending appropriate label precautions. ODM is classified as highly toxic to the honey bee on an acute contact and oral basis. The risk to honey bees and other nontarget insects is discussed in greater detail in the Risk Characterization section.

#### **b. Exposure and Risk to Nontarget Freshwater Aquatic Animals**

Acute and chronic risk quotients (RQs) for parent ODM are displayed on the page following, for aquatic animals (fish and invertebrates). The generation of aquatic exposure estimates (the numerators in the RQs) is discussed above in the environmental fate assessment. No chronic concern levels are exceeded (for fish or invertebrates). No acute high risk concern levels are exceeded. For invertebrates, acute endangered species concern levels are exceeded for application to grain sorghum and sweet corn.

**Risk quotients for freshwater fish and invertebrates**

Crop	Locality etc.	Estimated Environmental Concentration (EEC) for RQ numerator (ppb)			Risk Quotients by Crop/Locality			
					freshwater fish		freshwater invertebrate	
					acute <sup>1</sup>	chronic <sup>2</sup>	acute <sup>1</sup>	chronic <sup>2</sup>
					Toxic concentration (ppb)			
					730	2600	240	46
					Toxicity test type			
					LC50	NOAEC	LC50	NOAEC
					Exposure columnn for RQ calculation			
					peak	60 day	peak	21 day
		Peak	21 day	60 day	RQ = EEC / Toxic concentration			
Alfalfa for seed	Oregon	2.1	1.3	0.8	0.00	0.00	0.01	0.03
Cabbage	Imperial Valley, CA	3.4	2.6	1.6	0.00	0.00	0.01	0.06
Cabbage	Coastal Valley, CA	3.6	2.9	2.2	0.00	0.00	0.02	0.06
Citrus	Florida	7.0	4.6	2.5	0.01	0.00	0.03	0.10
Cotton	Imperial Valley, CA	3.1	1.9	1.3	0.00	0.00	0.01	0.04
Grain Sorghum	Kansas	10.9	6.8	3.7	0.01	0.00	0.05	0.15
Sweet Corn	Georgia	12.4	8.3	4.8	0.02	0.00	0.05	0.18
Field Corn	Ohio	6.5	4.6	2.6	0.01	0.00	0.03	0.10

<sup>1</sup>acute levels of concern for fish and aquatic invertebrates are RQ values at/below 0.5 (for acute high risk), 0.1 (restricted use), or 0.05 (endangered species)

<sup>2</sup>chronic levels of concern for fish and aquatic invertebrates are RQ values at/below 1.

**c. Estuarine and Marine Animals**

EFED does not currently have data to assess the toxicity and exposure to marine/estuarine fish and invertebrates from technical ODM. The guideline requirements (72-3 a, b, and c) are not fulfilled.

Chronic data are in reserve pending the results of the acute testing.

**d. Exposure and Risk to Nontarget Plants**

Currently, terrestrial plant testing is not required for pesticides other than herbicides except on a case-by-case basis. Terrestrial plant testing is not required for ODM.

Currently, aquatic plant testing is not required for pesticides other than herbicides and fungicides except on a case-by-case basis. Aquatic plant testing is not required for ODM.

**4. Endangered Species**

The following endangered species LOCs have been exceeded for ODM: estuarine shrimp, freshwater fish and invertebrates, mammals, and birds.

The Endangered Species Protection Program is expected to become final in the future. Limitations on the use of ODM will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

## **6. Risk Characterization**

### **a. Summary of Risks**

Parent ODM (S-[2-(ethylsulfinyl)ethyl]-O,O-dimethyl phosphorothioate) degrades rapidly by microbial-mediated metabolism to two types of metabolites, those that appear to be persistent and those that are non-persistent in the environment. The non-persistent metabolites include desmethyl ODM, ODM sulfide, desmethyl ODM sulfone, and ODM sulfone. These metabolites would not be expected to reach ground water or to persist in surface water.

The persistent metabolites include ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid. These metabolites are formed under aerobic conditions and appear to be mobile and may impact water resources.

The environmental fate database for ODM is not complete. Additional field dissipation, aerobic aquatic metabolism, and soil mobility information is requested to monitor for the persistent ODM metabolites.

There are no data available to assess ecological risk to animals from the metabolites. The EEC's used to assess risk to animals in the environment were based on parent ODM. Acute risk to birds and mammals is expected to be minimal. Chronic risk to birds and mammals is expected to be high. Because ODM is highly toxic to bees, risk to nontarget insects is presumed to be high. Aquatic risk from parent ODM and its non-persistent metabolites appears to be minimal. However, this conclusion does not apply to the metabolites which appear to be persistent, ODM thiol and 2-(ethyl sulfonyl) ethane sulfonic acid. EFED has no fate data on these metabolites and there is no apparent degradation of these compounds in the environment.

The ecotoxicity database for ODM is not complete. Additional acute estuarine/marine fish and invertebrate data is requested for parent ODM. Estuarine/marine fish and invertebrate chronic studies are held in reserve pending results of the acute testing. In addition, if the requested environmental fate information confirms that the metabolites are persistent in the environment, EFED will need additional ecotoxicity data on these metabolites.

Application information was derived from the Master Label (EPA Reg. 10163-220), EFED's evaluation includes crops that are not currently being marketed but may be reinstated for use. Maximum application rates were calculated and used for all modeling. The maximum number of allowed applications per season was also used. If the application rates are lowered to more typical use rates, fewer

applications are made, and the uses on the supplemental label are not reinstated, the total loading to the environment would be significantly lowered, resulting in a lower environmental exposure of ODM and its metabolites and therefore lower risk.

## **b. Characterization of the Fate and Transport**

The degradation of parent ODM is dependent on microbial-mediated metabolism; microbial-mediated metabolism occurs in both aerobic and anaerobic environments. Volatility is not a significant route of dissipation. All identified ODM metabolites are dephosphorylated and/or demethylated ODM. There are two groups of metabolites. The metabolites in the human health tolerance expression (ODM sulfone, desmethyl ODM, and desmethyl ODM sulfone) do not appear to be persistent in the environment. The metabolites that are not in the human health tolerance expression (ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid) do not appear to degrade, based on laboratory studies. However, these metabolites were not monitored in the field dissipation studies. Accumulation of the non-persistent metabolites considered in the tolerance statement are not likely, and the PRZM-EXAMS numbers support this conclusion. However, EFED expects that the metabolites that are not considered in the human health tolerance expression will persist and may accumulate in water.

### **Drinking water**

#### **(1) Surface Water**

EFED used modeling data (PRZM 2.3) to estimate surface water concentrations since no useful monitoring data could be obtained. These modeled EECs were used in both the ecological risk assessment and the human health assessment. For the crop sites modeled, the peak surface water EECs range from 2.9 to 33.7 ug/L and the chronic EECs range from 0.2 to 1.7 ug/L. ODM and its non-persistent metabolites are not expected, however, to persist in surface waters.

The estimated concentrations for both surface and ground water represent parent ODM, ODM sulfone, desmethyl ODM, and desmethyl ODM sulfone. These compounds appear to degrade rapidly in the environment, based on laboratory studies. However, modeling and estimation are not representative of ODM-thiol and 2-(ethylsulfonyl) ethane sulfonic since these metabolites do not appear to degrade in the laboratory studies. Environmental fate data are being requested for water resource and ecological considerations for ODM-thiol and 2-(ethylsulfonyl) ethane sulfonic.

#### **(2) Ground Water**

ODM and its non-persistent metabolites are not likely to be found in ground or surface water because of their relatively short half-life. The metabolites ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid are believed to be mobile and persistent and could reach both ground and surface water. ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid are the two metabolites that are the most likely to impact water resources. These two metabolites are not believed to have any mammalian toxicity and probably are not a human health concern in drinking water. However, since these are the most likely metabolites to impact water quality, and the ecological impact is unknown, additional environmental fate data will be required as part of the reregistration process.

Monitoring data for ODM in ground water is limited. The SCI-GROW model (screening model) was used to estimate the potential leaching of ODM and its non-persistent metabolites. Each of the “maximum concentration” ground water screening models predicted that little or no ODM would reach shallow ground water. Because of limited environmental fate data for the metabolites, parent ODM was used as a surrogate for modeling the non-persistent metabolites. Consequently, there is uncertainty in the ground water evaluation and modeling.

Results from the SCI-GROW ground water screening model predicted that the maximum chronic concentration of ODM and the non-persistent metabolites in shallow ground water (10-30 ft.) is not expected to exceed 0.006 ug/L for the majority of the use sites. This is considered to be an "upper bound" for these residues in ground water.

### c. Characterization of risk to nontarget species

The EEC's used to assess risk to animals in the environment were based on parent ODM. The fate and effects information available does not permit an evaluation of the additional risk associated with exposure to ODM metabolites. In order to evaluate the additional risk associated with exposure to ODM metabolites, first fate and transport data would be required for ODM thiol and ODM ESOES (2-(ethylsulfonyl) ethane sulfonic acid). Depending on the potential for aquatic exposure to these two metabolites, ecotoxicity information might then be required for the metabolites.

**Birds:** The overall **acute** risk to birds is expected to be low. Although the LOCs for restricted use, acute risk, and endangered species are marginally exceeded for the cabbage, cotton and citrus uses, and the LOCs for restricted use and endangered species are also marginally exceeded for the corn, sorghum, and alfalfa uses, environmental fate information suggests that parent ODM is not persistent in aerobic soil ( $t_{1/2} = 3.2$  days) and it is potentially mobile in various soils.

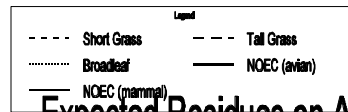
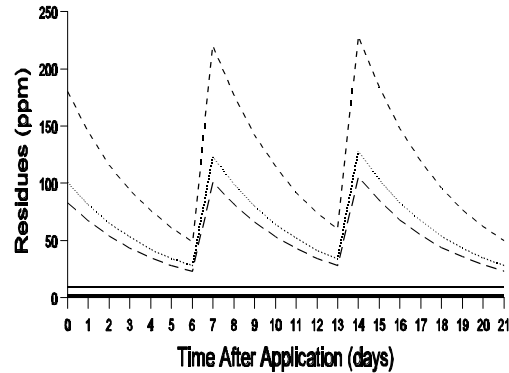
The overall **chronic** risk to birds from exposure to parent ODM and its non-persistent metabolites is expected to be high. In addition, if

environmental fate information confirms that the metabolites ODM thiol and 2-(ethyl sulfonyl) ethane sulfonic acid are persistent in the environment, risk from exposure to these metabolites is also expected to be high. The avian chronic LOC is exceeded for all application rates equal to and above 0.5 lbs ai/A (this includes cabbage, cotton, corn, sorghum, alfalfa, and citrus). The RQs range from 0.56 to 263, RQs above 1 are considered high risk. Although parent ODM is not expected to persist in the environment, EFED cannot dismiss the possible chronic effects based on these high LOCs. Northern bobwhite reproduction was affected at levels as low as 6.9 ppm (MRID 40747202) which is far below the majority of EECs calculated. EECs calculated using Hoerger and Kenaga and the FATE program (Section 3.a.), the number of days the predicted residues exceed the NOEC of 1.8 ppm were estimated and depicted in the diagrams below. Over a 21 day time period, the predicted residues constantly exceeded the LOC and rarely went near or below the NOEC.

In order to ascertain the length of time ODM and its non-persistent metabolites persist on animal feed items, GOWAN can submit foliar half-life information; if this information shows that parent ODM, and its non-persistent metabolites, do not persist on animal feed items, the expected chronic risk to birds would decrease.

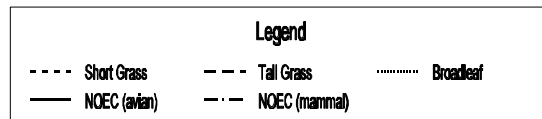
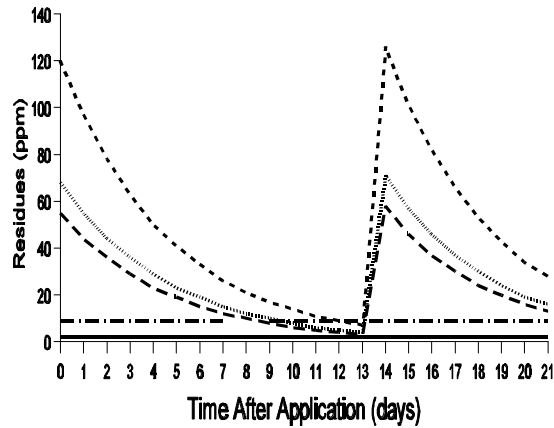
### Expected Residues on Cabbage and Cotton

Three Applications at 0.75 lb ai/A Each



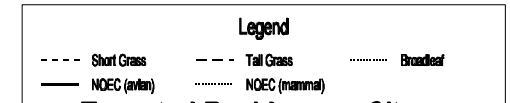
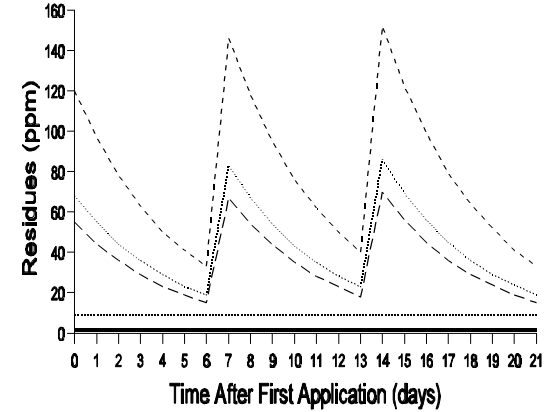
### Expected Residues on Alfalfa

Two Applications at 0.5 lb ai/A Each



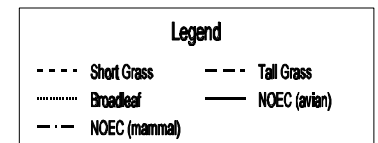
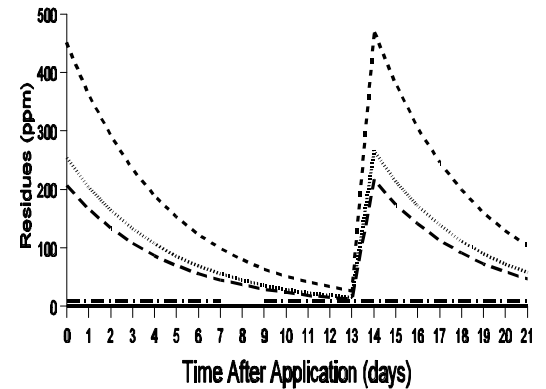
### Expected Residues on Corn and Sorghum

Three Applications at 0.5 lb ai/A Each



### Expected Residues on Citrus

Two Applications at 1.88 lb ai/A Each





**Mammals:** The overall **acute** risk to mammals is expected to be low. Although the LOCs for restricted use, acute risk, and endangered species are marginally exceeded for the meadow vole and least shrew on cabbage, cotton, corn, sorghum, alfalfa, and citrus, environmental fate information suggests that parent ODM is not persistent in aerobic soil ( $t_{1/2} = 3.2$  days) and it is potentially mobile in various soils.

The overall **chronic** risk to mammals is expected to be high. The mammalian chronic LOC is exceeded for all application rates equal to and above 0.5 lbs ai/A (this includes cabbage, cotton, corn, sorghum, alfalfa, and citrus) with the exception of exposure on fruit from the alfalfa, cabbage and cotton, and citrus uses. The RQs range from 0.11 to 8.44, RQs above 1 are considered high risk. Although parent ODM is not expected to persist in the environment, EFED cannot dismiss the possible chronic effects. The number of days the predicted residues exceed the NOEC of 9 ppm are shown in the above graphs. The predicted residues, over a 21 day time period, rarely go near or below the NOEC. In order to ascertain the length of time ODM and its toxic metabolites persist on foliage, GOWAN can submit foliar half-life information; if this information shows that ODM, and its non-persistent metabolites, does not persist on foliage, the expected chronic risk to mammals would decrease.

**Insects:** ODM is highly toxic to honey bees and therefore is a risk of significant exposure particularly with aerial and airblast application procedures. When bee kills occur, they are often associated with spray drift. However, given that ODM residues are not expected to be persistent in terrestrial environments, the potential for exposure will depend strongly on the timing of application relative

to periods of insect activity. Night applications of ODM are being used with increasing frequency by some farmers in Oregon and Washington, in order to reduce the risk of exposure to pollinators. Some species of plants are pollinated at night, e.g., by moths.

If ODM is applied at lower temperatures, the chemical will tend to degrade more slowly; however, at lower temperatures the activity of insects (and hence the potential for exposure) will also tend to be lower so that the potential for exposure is lower. In particular, pollination activity involves insect flight, which tends to be restricted to periods of relatively high ambient temperature. In particular, no significant honey bee pollination activity is expected below 50°F. Bumblebees, with larger body sizes than honeybees, can fly at somewhat lower temperatures. Smaller bee species tend to require higher ambient temperatures to fly.

The potential for exposure to bees will also depend on the species of plants that are flowering in and around the fields where pesticide is applied.

Some information on the relationship between specific pollinators and ODM use has been submitted in February 1998 by Ben Simko (Ag. Extension Service and Oregon St. U.) and certain alfalfa seed growers from Oregon (Andrews Seed Co., Northwest Alfalfa Seed Growers Assoc.), in connection with the organophosphate docket process. This material has been reviewed by the Biological and Economic Analysis Division (BEAD). It is reported that ODM is very useful in an integrated pest management scheme designed to protect the alfalfa pollinator *Megachile rotundata*. Use of the OPs Naled and ODM is considered to be valuable for protection of the pollinator in this system because of low persistence, and preferable to pyrethroids (the major alternative) for the same reason. Use in an IPM system reportedly permits ODM to be used at an average rate of about 0.5 ai/A, or about half the maximum label rate of 1 ai/A.

While the Agency does not have information on toxicity of ODM metabolites to nontarget insects, the experience with protection of *M. rotundata* in the alfalfa seed system suggests that the persistence of toxic residues is relatively low.

**Freshwater Fish:** The overall **acute** and **chronic** risk to freshwater fish is expected to be low. The acute endangered species LOC has been met, but not exceeded, at the registered maximum label rate of 0.75 lb ai/A\*yr (citrus). No chronic LOCs were exceeded. Parent ODM and its toxic metabolites degrade quickly in the aqueous environment. It is unlikely that it will remain in the water column for a long enough period of time to cause unreasonable risk to nontarget freshwater fish species.

In addition, if the requested environmental fate data confirms the presence of the metabolites ODM thiol and 2-(ethyl sulfonyl) ethane sulfonic acid in the environment, additional freshwater fish data will be requested.

**Freshwater Invertebrates:** The overall **acute** and **chronic** risk to freshwater invertebrates is expected to be low. The acute restricted use LOC has been slightly exceeded, at the registered maximum label rate of 0.75 lbs ai/A\*yr (citrus). The acute endangered species LOC has also been slightly exceeded at the 0.75 and 0.5 lbs ai/A\*yr use rates. No chronic LOCs were exceeded. Parent ODM and its toxic metabolites degrade quickly in the aqueous environment. It is unlikely that it will remain in the water column for a long enough period of time to cause unreasonable risk to nontarget freshwater invertebrate species.

In addition, if the requested environmental fate data confirms the presence of the metabolites ODM thiol and 2-(ethyl sulfonyl) ethane sulfonic acid in the environment, additional freshwater invertebrate data will be requested

**Estuarine and Marine Animals:** The overall **acute** risk to estuarine and marine animals cannot be determined at this time due to insufficient data. Estuarine/marine acute toxicity testing is requested.

Chronic data are in reserve pending results of the acute testing.

**Nontarget Plants:** Currently, terrestrial and aquatic plant testing is not required for pesticides other than herbicides except on a case-by-case basis. Nontarget plant testing is not required for ODM.

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## **Appendix C.1. Comparative Leaching Assessment based on the PATRIOT model**

In the RED, EFED used the PATRIOT model for estimating concentrations in ground water for the drinking water assessment. EFED is not currently using the results of the PATRIOT model for ODM because we have no official Tier II ground water model.. Also, PATRIOT modeling was conducted using an incorrect application rate as a model input for citrus. The modeling assumed two applications of 1.88 lbs ai/A for a total application rate of 3.76 lbs ai/a/yr. The correct application rate is 0.375 lb ai/A \* 2 applications for a total of 0.75 lb ai/A/yr. Instead of the PATRIOT modeling, EFED is currently using the results of the SCI-GROW model for drinking water assessment. Therefore, the PATRIOT modeling details for ODM are included in the appendix.

The PATRIOT model was used to perform a comparative leaching assessment using the Pesticide Root Zone Model (PRZM) for ODM and its non-persistent metabolites (ODM sulfone, desmethyl ODM sulfone, and desmethyl ODM). PRZM is a one-dimensional, dynamic, compartmental model that can be used to simulate pesticide movement in unsaturated soil systems within and immediately below the root zone.

Because of a lack of environmental fate data on the non-persistent metabolites, information derived from characteristics of parent ODM was used. EFED has concluded that this was a reasonable assumption (refer to the environmental fate section for additional information). The persistent metabolites ODM thiol and 2-(ethylsulfonyl) ethane sulfonic acid were not modeled.

PATRIOT modeling for “ODM” (parent ODM and the non-persistent metabolites) was conducted for citrus in Florida, sweet corn in Georgia, field corn in Iowa, sorghum in Kansas, cotton, and alfalfa grown for seed in the Central Valley of California, cabbage in the coastal valleys of California and for alfalfa grown for seed in Oregon. The leaching of “ODM” was then compared to the potential leaching of atrazine and bromide. Atrazine was selected because it is a well characterized corn herbicide and is known to leach to ground water. Bromide was selected because it is an anion in aqueous environments, resists binding, will move with the water front and is often used as a tracer for ground water monitoring studies. Additional assumptions and input from the PATRIOT modeling are displayed in Appendix C.2.

No significant leaching of ODM or the non-persistent metabolites was predicted to occur on any of the sites or crops modeled using PATRIOT. Comparative modeling predicted that up to 47% of atrazine could leach, while 40 to >86 % of the bromide tracer could leach when modeled under the same conditions and with the same soils.

Although ODM and the non-persistent metabolites are relatively mobile, they were not expected to leach because of their relatively short aerobic soil half-life ( $T_{1/2} = 3.2$  days). Since ODM use in California, Oregon, and other areas occurs mostly on Hydrologic Group C and Hydrologic Group D soils, there is greater potential for surface water runoff, and less potential for leaching in these areas. The PATRIOT modeling supports this conclusion.

Estimated Mass Leached - % of Applied								
State/ Crop	FL Citrus	GA Sweet Corn	IA Field Corn	KS Sorghum	CA (Central) Cotton	CA (Central) Alfalfa.	CA (Coastal) Cabbage	OR Alfalfa (Seed)
Soil Hydro. Gp.	B/D	C	B	C	C and D	C and D	D	C
Mass Applied (lb a.i./acre/seas on)	3.76	1.5	1.5	1.5	1.5	1.0	2.25	1.0
“ODM”	0.8	3-6	0	0	0 - 1	0 - (<5)	0	0
Atrazine	27	44-47	0	0	0 -10	0 - 19	0	0
Bromide	86	79-80	40	67	12 - 70	23 - 67	82	53

“ODM” collectively represents parent ODM and the metabolites ODM sulfone, desmethyl ODM sulfone, and desmethyl ODM



## **Appendix C.2:**

### **Health Advisory Calculations for Drinking Water and PATRIOT Model Inputs**

Lifetime Health Advisory for Drinking Water

Formulas:

$$\text{DWEL} = \frac{(\text{RfD}) (70 \text{ kg})}{2 \text{ L/d}}$$

$$\text{Lifetime HA} = \text{DWEL} \times \text{RSC}$$

RfD - Reference Dose - estimate of daily exposure likely to be without appreciable risk of deleterious health effects in the human population (including sensitive subgroups) over a lifetime.

DWEL - Drinking Water Equivalent - concentration in drinking water that is not expected to cause any adverse non-carcinogenic health effects over a lifetime of exposure.

RSC - Relative  
Source Contribution - Amount of exposure from drinking water relative to other sources

Assumptions:

$$\text{RfD} = 0.005 \text{ mg/kg/day (USEPA, 1997)}$$

70 kg Adult consumes 2 L/day of drinking water

$$\text{RSC} = 20\%$$

Calculation:

$$\text{DWEL} = \frac{0.005 \text{ mg/kg/day} \times 70 \text{ kg}}{2 \text{ L/day}} = 0.0175 \text{ mg/L}$$

Lifetime HA = 3.15 mg/L x 0.20 = 0.0035 mg/L = 3.5 ug/L

Input for PATRIOT Modeling - ODM

Koc = 26  
Aerobic Soil T1/2 = 3.2 days

Crop: Citrus - Used Grapefruit scenario  
State: FL  
MLRA: 156  
Soil: Pineda (3940)  
Soil Hy. Gp: B/D  
Depth G/W: 61 cm (2 feet)  
Met. Data: 1955-1964  
App. Rate: 1.88 lb ai x 2 app/season = 3.76 lb ai/season  
Corr. for irr. and evaporation

Crop: Corn-Sweet  
State: GA  
MLRA: 133  
Soil: Cowarts (249, 251) - Sandy Loam  
Soil Hy. Gp: C  
Depth G/W: 120 cm (3.9 feet)  
Met. Data: 1974-1983  
App. Rate: 0.5 lb ai x 3 app/season = 1.5 lb ai/season  
Corr. for irr. and evaporation

Crop: Corn-Field  
State: IA  
Soil: Marshall (4644) - Silty Clay Loam  
Soil Hy. Gp: B  
Depth G/W: 164 cm (5.4 feet)  
Met. Data: 1961-1970  
App. Rate: 0.5 lb ai x 3 app/season = 1.5 lb ai/season  
Corr. for irr. and evaporation

Crop: Sorghum  
State: KS  
Soil: Dennis Silt Loam (15489, 15490)  
Soil Hy. Gp: C  
Depth G/W: 103 cm (3.3 feet)  
Met. Data: 1969-1978  
App. Rate: 0.5 lb ai x 3 app/season = 1.5 lb ai/season  
Corr. for irr. and evaporation

Crop: Cotton  
State: CA (Central)  
Soils: Redding (1680), Capay (1790), Garces (2801), Armona (2096)  
Soil Hy Gp: C and D  
Depth G/W: 174 cm (5.7 feet)  
Met. Data: 1974-1983  
App. Rate: 0.5 lb ai x 3 app/season = 1.5 lb ai/season  
Corr. for irr. and evaporation

Crop: Alfalfa (Seed)  
State: CA (Central)  
Soils: Redding (1680), Capay (1790), Garces (2801), Armona (2096)  
Soil Hy. Gp: C and D  
Depth G/W: 174 cm (5.7 feet)  
Met. Data: 1974-1983  
App. Rate: 0.5 lb ai x 2 app/season = 1.00 lb ai/season  
Corr. for irr. and evaporation  
Cropping dates for CA Wheat used as surrogates for alfalfa

Crop: Cabbage  
State: CA (Coastal)  
Soil: Antioch (1176))  
Soil Hy. Gp: D  
Depth G/W: 177 cm (5.8 feet)  
Met. Data: 1974-1983  
App. Rate: 0.75 lb ai x 3 app/season = 2.25 lb ai/season  
Corr. for irr. and evaporation  
Crop: Alfalfa (Seed)

State: OR  
Soil: Longbranch (16756)  
Soil Hy. Gp: C  
Depth G/W: 165 cm (5.4 feet)  
Met. Data: 1974-1983 (Boise, ID - W24131)  
App. Rate: 0.5 lb ai x 2 app/season = 1.0 lb ai/season  
Corr. for irr. and evaporation

<b>Appendix C.3. Specific Information used as the Basis for PRZM Modeling.</b>					
Crop	Location, (Soil), Hydrologic grouping, and (MLRA)	Maximum Labeled Rate (lb ai/A)	Emergence Date	Maturity Date	Harvest Date
Alfalfa <sup>1</sup>	Malheur County, OR (Fury silty clay loam), Group C, (MLRA 23)	2.25 lb (3 x 0.75 lbs ai at 14-day intervals)	March 15	July 23	July 31
Cabbage <sup>2</sup>	Imperial Valley, CA (Lerdo clay loam), Group C, (MLRA 17)	2.25 lb (3 x 0.75 lbs ai at 14-day intervals)	September 1	December 23	December 31
Cabbage <sup>3</sup>	Coastal Valley, CA (Pico sandy loam), Group B (MLRA 14)	2.25 lb (3 x 0.75 lbs ai at 14-day intervals)	February 1	May 5	May 12
Citrus <sup>4</sup>	Osceola County, FL, (Adamsville sand), Group C, (MLRA 156a)	0.75 lb (2 x 0.375 lb ai/A at 14-day intervals)	May 11	July 17	August 1
Cotton <sup>5</sup>	Imperial Valley, CA (Lethent clay loam), Group D, (MLRA 17)	2.25 lb (3 x 0.75 lbs ai at 14-day intervals)	April 15	September 1	September 22
Field Corn <sup>6</sup>	Pottawattamie County, IA (Marshall silty clay loam), Group C,	1.5 lb (3 x 0.50 lbs ai at 7-day intervals)	May 21	September 26	October 11
Sweet Corn <sup>8</sup>	Crisp County,	1.5 lb	April 11	August 28	September 12

<sup>1</sup> Emergence, maturity, harvest, and typical window of potential application dates came from Dr. Ben Simko, Extension Agent, Malheur County, OR. The number of applications and the use rates of 0.75 lbs ai/A/application (2.25 lbs ai/A/season) came from a Gowan fax. The EFED surface water modeler assumed the dates used in the model.

<sup>2</sup> Emergence, maturity, harvest and typical window of potential application dates came from Dr. Larry Godfrey, Extension Agent, CA. The number of applications and the use rates of 0.75 lbs ai/A/application (2.25 lbs ai/A/season) came from a Gowan fax. This was a California site with a non-California use rate of 0.75 lbs ai/A/application (2.25 lbs ai/A/season). The California rate was 0.5 lbs ai/A/application per a Gowan fax. This scenario and the 0.75 lb ai/A/application rate were used as a surrogate for other vegetable crops since it was the crop with the highest use rate and since most ODM use is in California.

<sup>3</sup> Emergence, maturity, harvest, and typical window of potential application dates came from Dr. Bill Chaney, Extension Agent, CA. The number of applications and the use rates of 0.75 lbs ai/A/application (2.25 lbs ai/A/season) came from a Gowan fax. This was a California site with a non-California use rate of 0.75 lbs ai/A/application (2.25 lbs ai/A/season). The California rate was 0.5 lbs ai/A/application per a Gowan fax. This scenario and the 0.75 lb ai/A/application rate were used as a surrogate for other vegetable crops since it was the crop with the highest use rate and since most ODM use is in California.

<sup>4</sup> Emergence, maturity, and harvest dates were in standard EFED Florida citrus scenario. Application dates were assumed by surface water modeler (Jim Breithaupt). The use rate of 1.88 lbs ai/A x 2 applications came from a Gowan fax.

<sup>5</sup> Emergence, maturity, harvest, and typical window of potential application dates came from Dr. Larry Godfrey, Extension Agent, CA. The three applications of 0.75 lb ai/a/application (2.25 lbs ai/A) came from a Gowan fax.

<sup>6</sup> Emergence, maturity, and harvest dates were in standard EFED Iowa Corn scenario. Application dates were assumed by surface water modeler (Jim Breithaupt). The use rate of 1.88 lbs ai/A x 2 applications came from a Gowan fax.

<sup>7</sup> Emergence, maturity, harvest, and typical window of potential application dates came from Dr. Leroy Brooks, Extension Agent, KS. The three applications of 0.50 lb ai/a/application (1.50 lbs ai/A/season) came from a Gowan fax.

<sup>8</sup> Emergence, maturity, and harvest dates were in standard EFED Georgia corn scenario. The application dates were assumed by the surface water modeler (Jim Breithaupt). The three applications of 0.50 lb ai/a/application (1.50 lbs ai/A/season) came from a Gowan fax.

**Appendix C.4.** Comparison of surface water modeling results obtained with PRZM Model Version 2.3 to Results obtained with PRZM Version 3.12

Crop	Maximum ( $\mu\text{g} \cdot \text{L}^{-1}$ )	4 Day ( $\mu\text{g} \cdot \text{L}^{-1}$ )	21 Day ( $\mu\text{g} \cdot \text{L}^{-1}$ )	60 Day ( $\mu\text{g} \cdot \text{L}^{-1}$ )	90 Day ( $\mu\text{g} \cdot \text{L}^{-1}$ )	Long-term Mean* ( $\mu\text{g} \cdot \text{L}^{-1}$ )
Alfalfa for seed (Oregon, PRZM 3.12)	2.1	1.9	1.3	0.8	0.6	0.2
Alfalfa for seed (Oregon, PRZM 2.3)	2.9	2.6	1.7	1.0	0.7	0.2
Cabbage (Imperial Valley, CA, PRZM 3.12)	3.4	3.2	2.6	1.6	1.1	0.5
Cabbage (Imperial Valley, CA, PRZM 2.3)	4.2	4.0	3.1	2.5	2.1	0.6
Cabbage (Coastal Valley, CA, PRZM 3.12)	3.6	3.4	2.9	2.2	1.7	0.5

Cabbage (Coastal Valley, CA, PRZM 2.3)	4.0	3.7	2.9	2.3	1.7	0.4
Citrus (Florida, PRZM 3.12, 0.375 lb ai/A *2 apps)	7.0	6.4	4.6	2.5	1.8	0.5
Citrus (Florida, PRZM 2.3, 1.88 lbs ai/A * 2 apps)	33.7	30.2	19.7	10.4	7.1	1.7
Cotton (Imperial Valley, CA, PRZM 3.12)	3.1	2.8	1.9	1.3	0.9	0.2
Cotton, (Imperial Valley, CA, PRZM 2.3)	3.2	2.8	2.1	1.6	1.1	0.3
Grain Sorghum (Kansas, PRZM 3.12)	10.9	9.7	6.8	3.7	2.7	0.7
Grain Sorghum (Kansas, PRZM 2.3)	10.5	9.1	5.9	3.1	2.1	0.5



Sweet Corn (Georgia, PRZM 3.12)	12.4	11.5	8.3	4.8	3.4	0.9
Sweet Corn (Georgia, PRZM 2.3)	11.8	10.4	7.0	3.8	2.6	0.6
Field Corn (Ohio, PRZM 3.12)	6.5	5.9	4.6	2.6	1.8	0.5
Field Corn (Iowa, PRZM 2.3)	6.1	5.4	3.7	2.0	1.4	0.4
* Upper 90% confidence bound on the 36 year mean with the variance calculated from the annual means.						